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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,056	03/15/2005	Josef Seidl	1998.012US1	9037

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EXAMINER	
HOBBS, MICHAEL L	

ART UNIT	PAPER NUMBER
1797	

NOTIFICATION DATE	DELIVERY MODE
06/25/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

request@slwip.com

Office Action Summary	Application No.	Applicant(s)	
	10/528,056	SEIDL ET AL.	
	Examiner	Art Unit	
	MICHAEL HOBBS	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14 and 16-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/11/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/11/2009 has been entered.

2. Claims 14, 16-34 are pending further examination upon the merits.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 14, 16-21 and 23-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kearney (US 5,424,209) in view of Blumenfeld et al. (US 2003/0151735 A1) and in further view of Bacus (IS 4.175.860).

7. For claim 14, Kearney discloses an automated cell culture device that includes a bioreactor or cell culture chamber includes a heating element or incubation equipment for cultivating cells (col. 5 lines 59-62; col. 6 lines 24-26). The bioreactor and heating element are fully capable of adjusting the conditions within the bioreactor to individual cell lines if needed. Kearney further discloses that the bioreactor can be used with an automated microscope/CCD and a robotic X-Y-Z translator (col. 20 lines 25-28), but does is silent regarding the software or the optics assembly.

8. Blumenfeld discloses a CCD (CCD 608) or camera that includes a viewing optics assembly (assembly 617) which is being interpreted as a microscope attachment and where the CCD and optics assembly are attached to a moveable platform (platform 620; [0170]; [0181]). The carriage moves the lens across the slide during scanning where

this movement is controlled by a computer implementing software ([0055]) and the focusing or imaging is automatically controlled by the software of Blumenfeld ([0077]) where this is being interpreted as "automatically determine cell contours". The computer (computer 8) of Blumenfeld stores the image ([0064]; [0066]) as image data and this process of storing is being interpreted as being performed by the imaging software. Therefore, it would be obvious to one of ordinary skill in the art to employ the optics system as suggested by Blumenfeld in order to observe the cells of Kearney. The suggestion for doing so at the time would have been in order to scan or image a biological sample or a portion of that sample ([0047]).

9. Kearney and Blumenfeld are silent regarding a software configured to automatically recognize cell contours or images when the camera moves past the cell culture chamber.

10. Bacus discloses a dual resolution method and apparatus for the automated classification of biological cells that for claim 1 includes pre-screens a slide for the purpose of finding dark objects or contours over a pre-determined threshold limit and the location of the object is written into an electronic memory (col. 4 lines 50-54). This memory information is then used to operate the controllers for positioning the stage for the cells to be subjected to further testing (col. 4 lines 54-58). This is being interpreted as reading on the control software recognizing the contours on a subsequent pass of the chamber. Also, while Bacus does not explicitly disclose controlling software, a software package to control the stage and store and retrieve image data is an implicit feature of the imager of Bacus. Therefore, it would have been obvious to one of

ordinary skill in the art to employ the controller of Bacus in order to "recognize" already identified cells and return the imager to the location of the cells within Kearney and Blumenfeld. The suggestion for doing so at the time would have been in order to have accurate classification or identification of the cells (col. 4 lines 57-59).

11. For claim 15, the camera of Kearney is fully capable of recognizing stored contours when the camera is indexed.

12. Regarding claims 16, and 27, Kearney discloses that culture media is sent to the bioreactor from sample reservoirs (2) via fluid pathways where the nutrient media is oxygenated by a gas source such as a pressurized gas bottle (col. 6 lines 1-3, 12-14). The nutrient media and gas source are fully capable of providing a continuous source of culture media and gas to the bioreactor. Furthermore, the heating of the bioreactor is controlled by a heat sink with a Peltier-type heating/cooling unit that includes an embedded heat sensor for monitoring temperature (col. 6 lines 24-26). The temperature sensor is connected to an on-board computer or controller that controls the operation of the Peltier heating/cooling device (col. 6 lines 27-30). Morphological analysis of the cells occurs through an automated microscope or CCD camera system (col. 20 lines 25-28). Also, cell parameters such as dissolved oxygen content of the media or acidity are sensed by flow cell electrodes within the flow cell (col. 15 lines 32-34). The data from these electrodes form the basis for software controlled decisions to refresh the volume of gas within the oxygentator (col. 15 lines 34-37, oxygenator 6). The computer and software are fully capable of optimizing the conditions within the bioreactor based on feedback from the sensors.

13. With regards to claims 17 and 18, Kearney discloses that the bioreactors are connected in series (col. 20 lines 43-45) or in parallel (col. 6 lines 1-2).

14. For claims 19 and 20, Kearney also discloses a circulating peristaltic pump for circulating the media through the plurality of pathways (col. 5 lines 63-67) and that the gas flow is controlled by a series of T-unions (38,112) that direct the airflow through a high pressure valve and into a membrane oxygenator (oxygenator 6; col. 14 line 66 through col. 15 line 4). Regarding claim 21, the embedded temperature system was discussed above.

15. With regards to claim 23, Kearney discloses monitoring the temperature which is being interpreted as permanent monitoring of the temperature as discussed above. Kearney discloses a computer to control the action of the bioreactor which receives data from the sensors such as microscopic observation of the cells, temperature measurement and measuring cell parameters such as pH. The computer uses this data to control the reaction as was discussed above. Also, for claim 24, data from the sensors was analyzed by soft-ware as was discussed above.

16. Regarding claim 25, Kearney further discloses that bioreactors are mounted within recess of the aluminum heat sink that includes the heating element (col. 6 lines 24-26). Furthermore, it would be obvious to one of ordinary skill in the art to employ a plurality of culture chambers in order to increase the throughput of the process. See MPEP 2144.01 VI (B). For claim 26, the chambers of Kearney are fully capable of providing indirect co-culturing.

17. With regards to claims 28 and 29, Kearney discloses that the bioreactors are connected in series (col. 20 lines 43-45) or in parallel (col. 6 lines 1-2).

18. For claims 30 and 31, Kearney also discloses a circulating peristaltic pump for circulating the media through the plurality of pathways (col. 5 lines 63-67) and that the gas flow is controlled by a series of T-unions (38,112) that direct the airflow through a high pressure valve and into a membrane oxygenator (oxygenator 6; col. 14 line 66 through col. 15 line 4).

19. With regards to claim 32, Kearney discloses monitoring the temperature which is being interpreted as permanent monitoring of the temperature as discussed above. Kearney discloses a computer to control the action of the bioreactor which receives data from the sensors such as microscopic observation of the cells, temperature measurement and measuring cell parameters such as pH. The computer uses this data to control the reaction as was discussed above.

20. Claims 22, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kearney (US 5,424,209) in view of Blumenfeld et al. (US 2003/0151735 A1) and in further views of Bacus (IS 4.175.860) and Pfaller (US 6,329,195 B1).

21. Kearney, Blumenfeld and Bacus are silent regarding a gas-permeable membrane with cells on both sides of the membrane.

22. Pfaller discloses a cell culture for continuously supplying culture media to the cells via inflow and outflow openings. For claims 22 and 33, Pfaller discloses that the

culture chamber is divided by a gas-permeable membrane (5) where the membrane can culture to mono-layers of cells. The inlets and outlets provide for the continuous and homogeneous replacement of culture medium (col. 2 lines 55-58). Also, two different nutrient compositions can be perfused through the top (apical) and bottom (basal) side of the growth support (col. 2 lines 58-62). Since Pfaller discloses that two different culture media can be perfused through the culture chamber, it would be obvious to one of ordinary skill in the art to employ the double chamber of Pfaller in order to co-culture the cells within Kearney and Blumenfeld. The suggestion for doing so at the time would have been in order to provide organotypic culture conditions within the chamber (col. 2 line 62).

23. With regards to claim 34, Kearney discloses monitoring the temperature which is being interpreted as permanent monitoring of the temperature as discussed above. Kearney discloses a computer to control the action of the bioreactor which receives data from the sensors such as microscopic observation of the cells, temperature measurement and measuring cell parameters such as pH. The computer uses this data to control the reaction as was discussed above. While not specifying that this is continuous, the observation system of Kearney is fully capable of monitoring the cell chamber in a continuous fashion.

Response to Arguments

24. Applicant's arguments with respect to claims 14, 16-32 have been considered but are moot in view of the new ground(s) of rejection. The new grounds of rejection are in

view of Bacus which discloses a controller that automatically identifies stores and moves a stage back to the place where a target cell was identified.

25. With regards to Applicant's arguments regarding Kearney and Blumenfeld, the deificiences of these references have been corrected by the newly applied reference of Bacus.

Conclusion

26. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL HOBBS whose telephone number is (571)270-3724. The examiner can normally be reached on Monday-Thursday 7:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. H./
Examiner, Art Unit 1797

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797